CMS

ICD-9-CM Proposal

FRACTIONAL FLOW RESERVE AND INTRAVASCULAR PRESSURE MEASUREMENT

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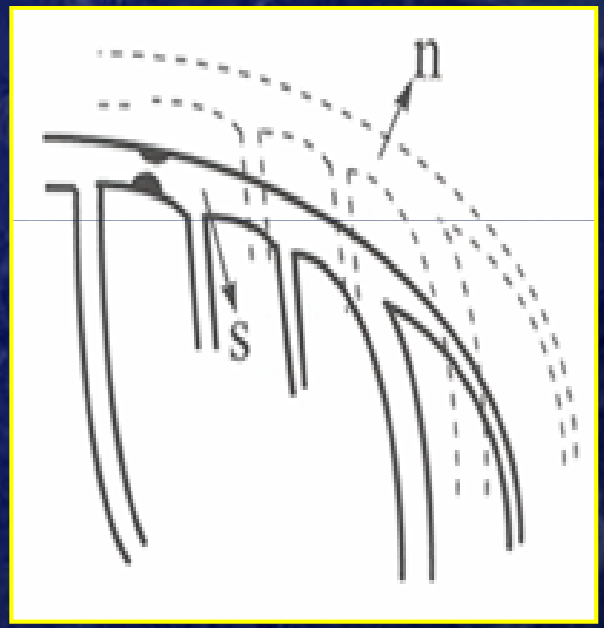
FFR & Intravascular Pressure Measurement

- Improves patient outcomes
- Saves procedure time
- Reduces costs
- Used for both coronary and non-coronary vessels
- Currently is not tracked, resulting in inadequate reporting

Fractional Flow Reserve

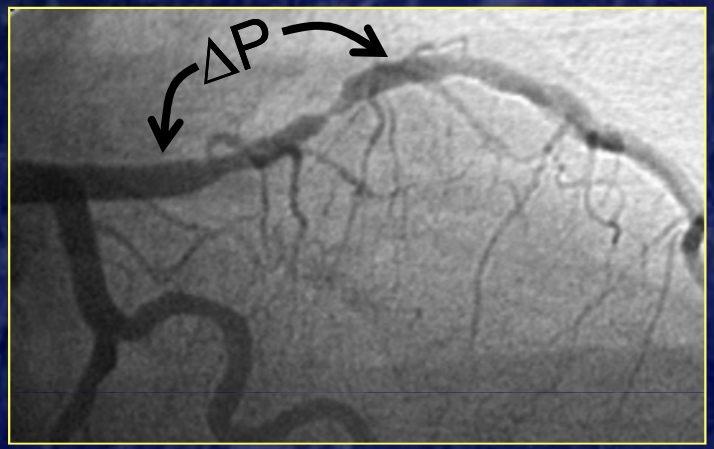
Definition of FFR

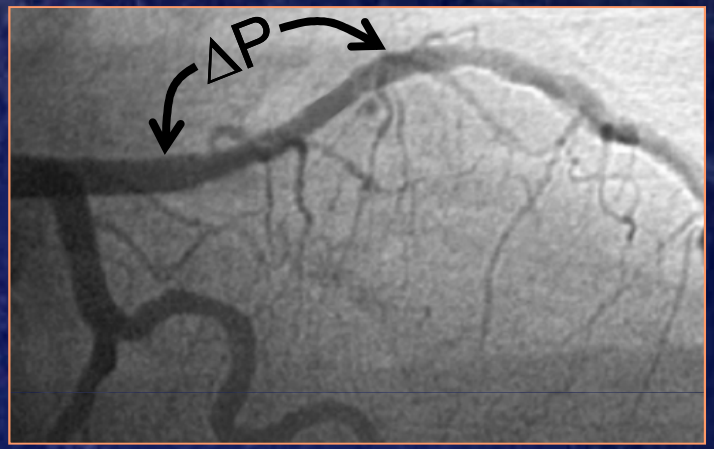
FFR is the ratio between maximal myocardial flow in the stenotic vessel and the maximal myocardial flow in the same vessel without stenosis

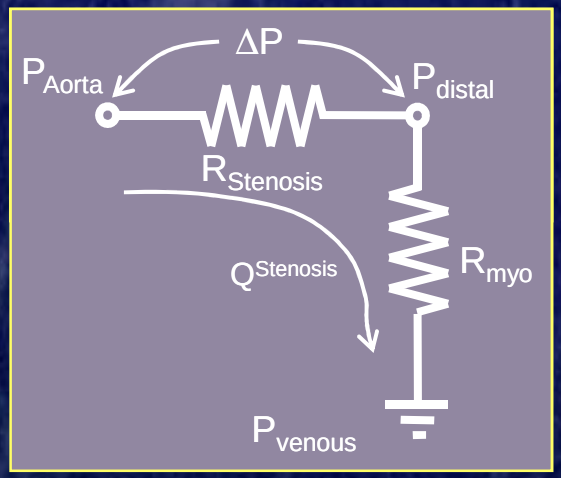


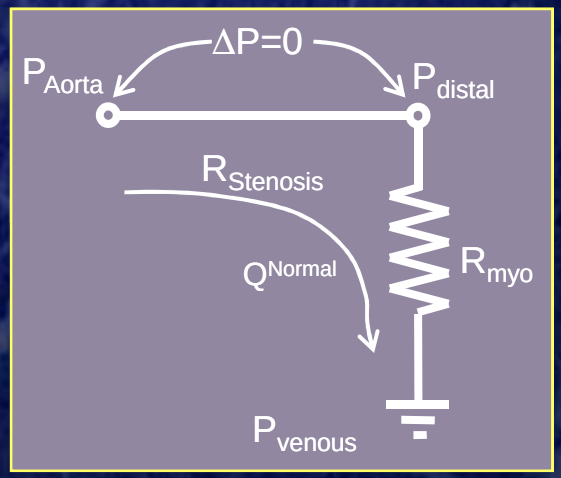
Fractional Flow Reserve

Definition of FFR







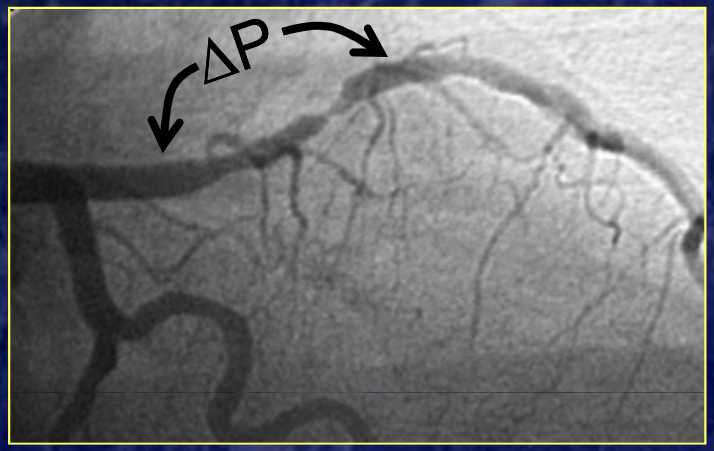


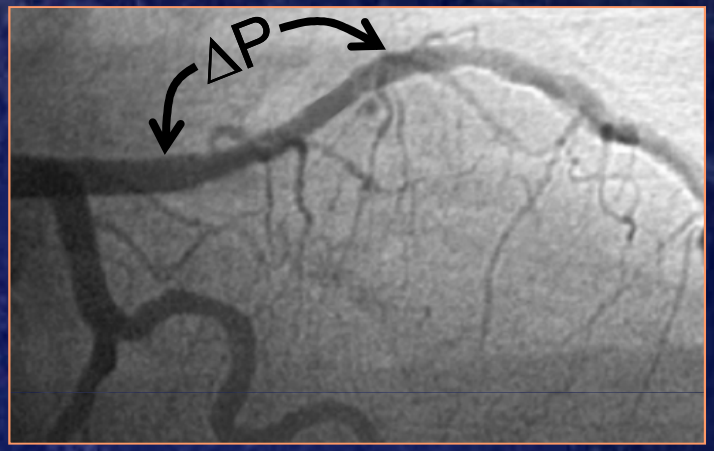
$Q^{Stenosis} = (P_d - P_v) / R_{myo}$

$Q^{Normal} = (P_A - P_v) / R_{myo}$

Fractional Flow Reserve

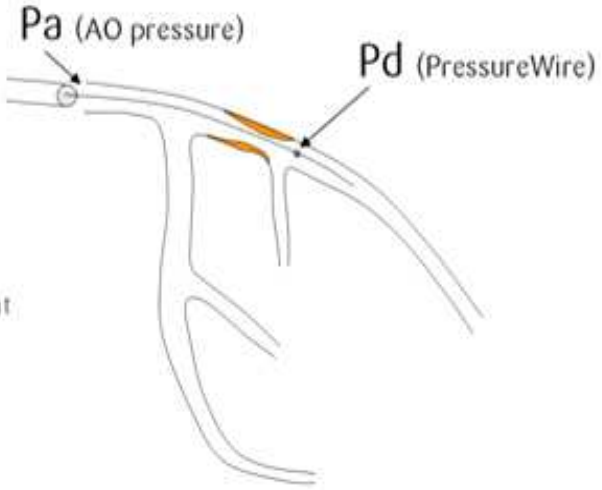
Definition of FFR





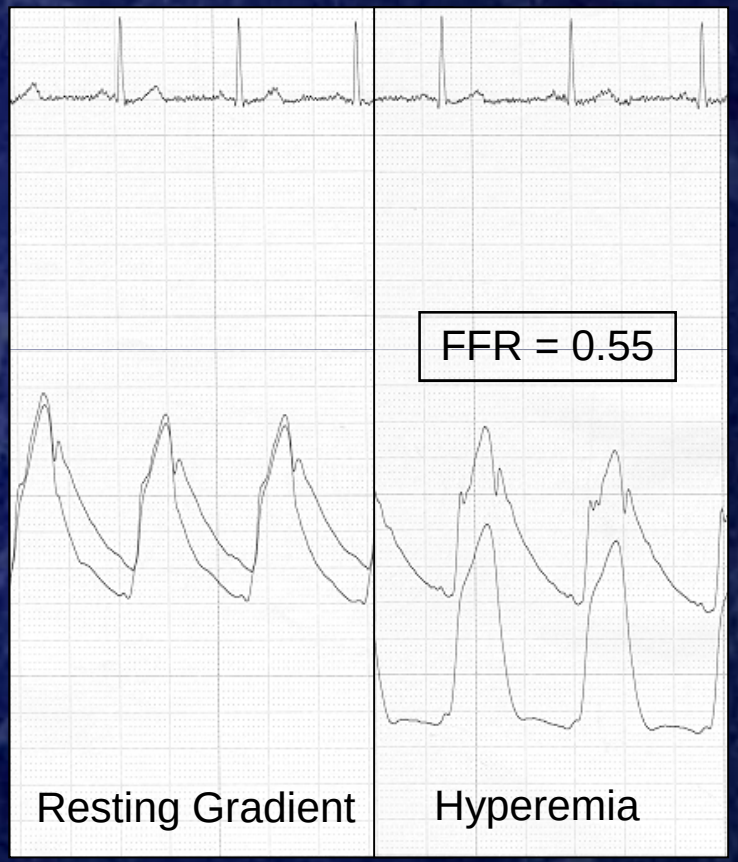
$$FFR_{myo} = \frac{Pd}{Pa}$$

(assuming linear pressure/flow relationship present during maximum flow, hyperemia)



Fractional Flow Reserve Concepts

Abnormal FFR_{myo}



Fractional Flow Reserve Concepts

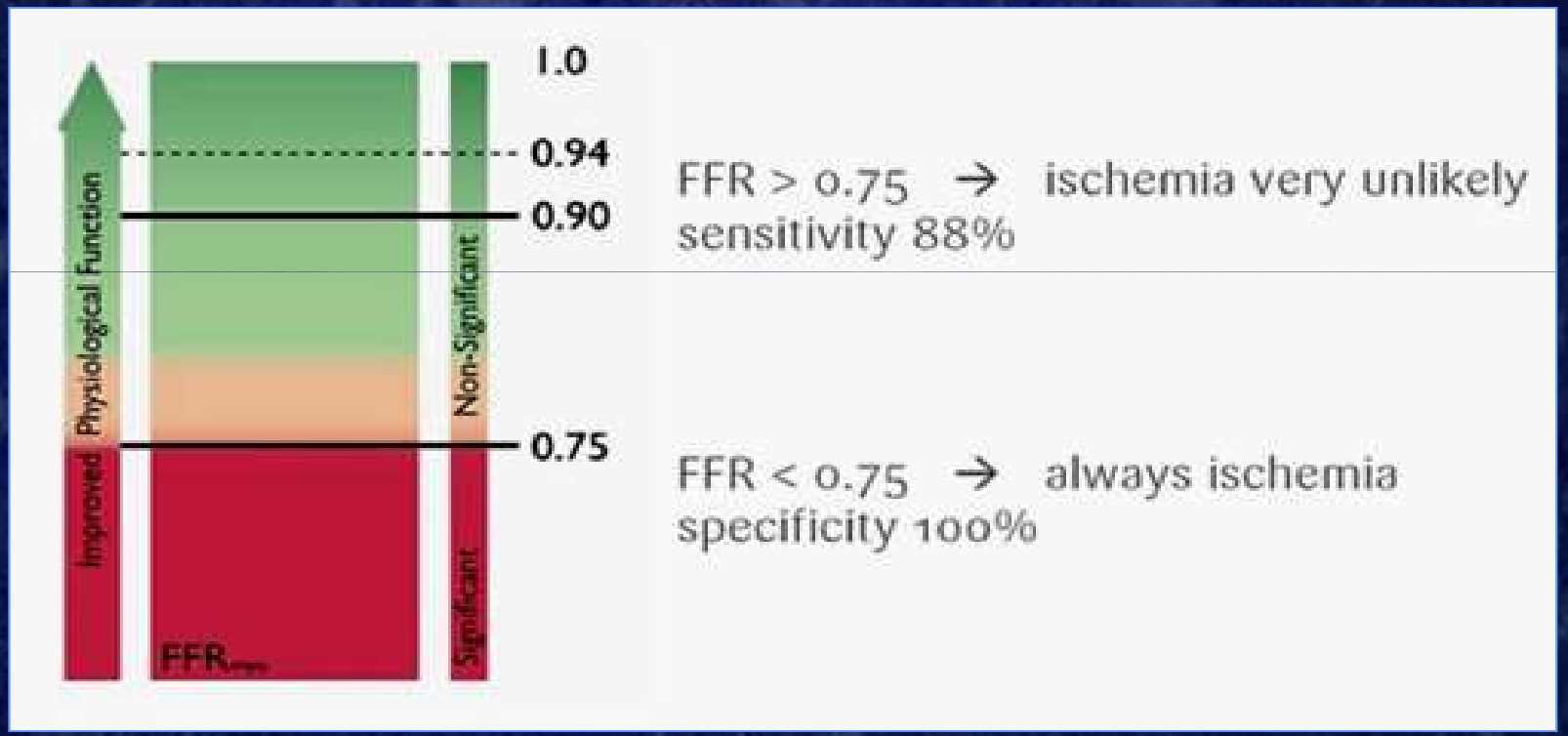
Correlative Studies

Reference	n	Ischemic Test	Cut-off	Accuracy
Pijls	60	X-ECG	0.74	97
DeBruyne	60	X-ECG/SPECT	0.66	87
Pijls	45	X-ECG/SPECT/pacing/DSE	0.75	93
Bartunek	37	DSE	0.67	90
Abe	46	SPECT	0.75	91
Chamuleau	127	SPECT	0.74	77
Caymaz	40	SPECT	0.75	95
Fearon	10	SPECT	0.75	95
DeBruyne	57	SPECT	0.78	85
Jiminez-Navarro	21	DSE	0.75	90
Meuwissen	151	SPECT	0.74	75
Usui	167	SPECT	0.75	79
Yanagisawa	165	SPECT	0.75	76

AHA Scientific Statement, Circulation 2006

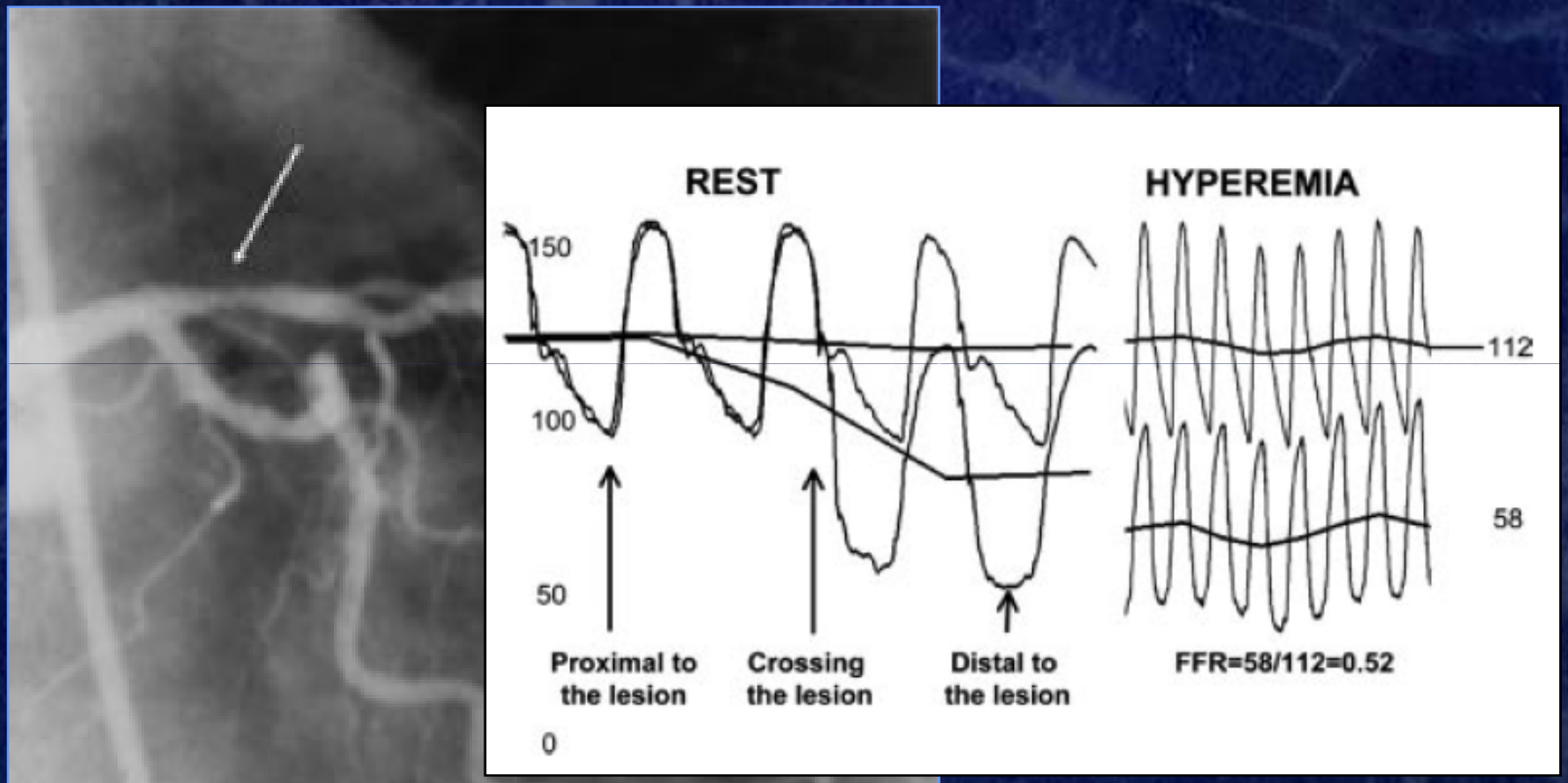
Fractional Flow Reserve

Definition of FFR



Fractional Flow Reserve

Case Example



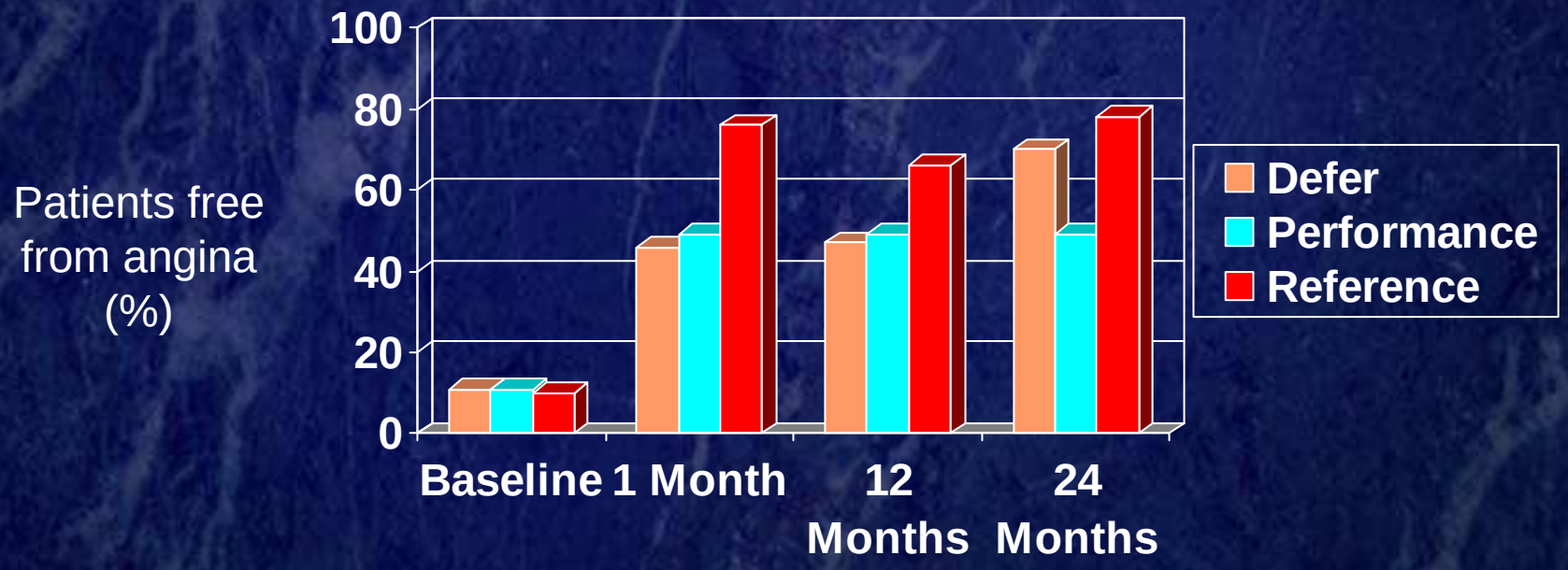
Physiological Assessment of Coronary Artery Disease in the Cardiac Catheterization Laboratory, Circulation 2006

Deferral of PTCA Based on FFR

325 patients referred for PTCA without documented ischemia

If FFR >0.75, randomized to Defer (91) or Performance (90) groups

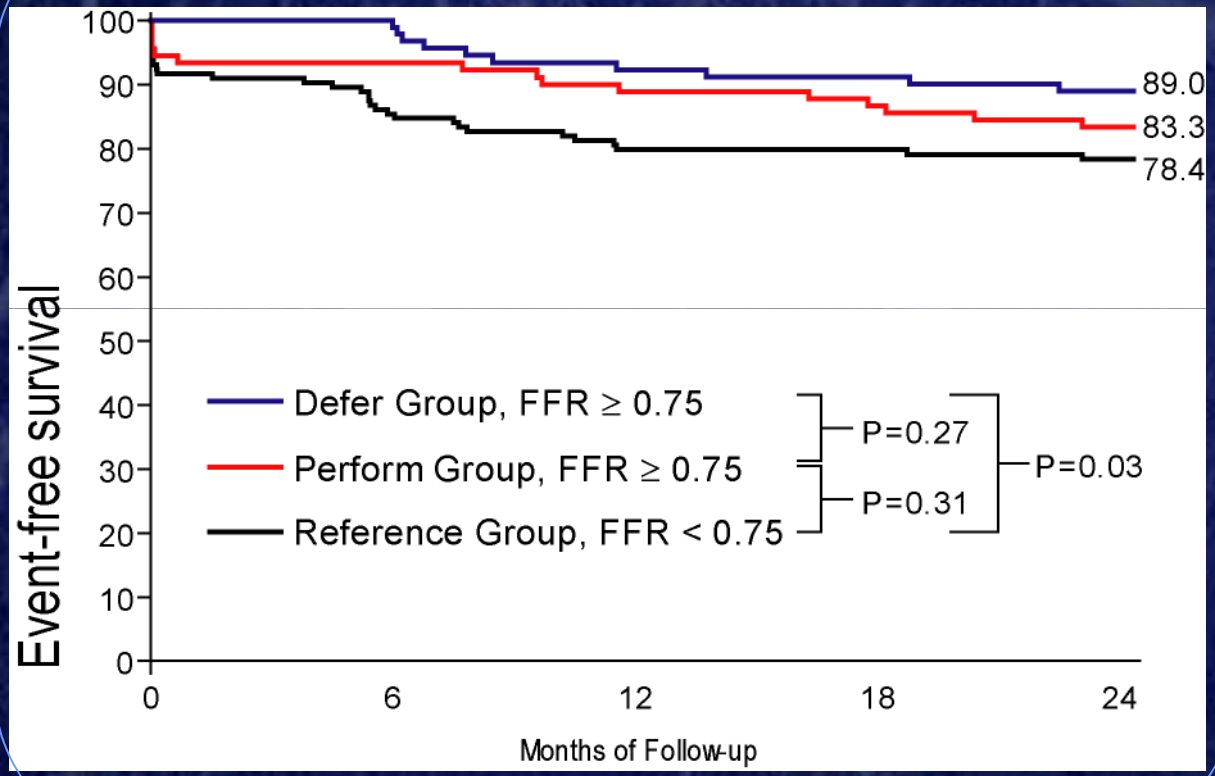
If FFR <0.75, PTCA performed, Reference group (144)



Bech et al, Circulation 2001

THE DEFER STUDY: 2 YEAR EVENT-FREE SURVIVAL

Circulation 2001; 103:2928-34)



Non-culprit lesions generally do not need to be treated!

Mortality / AMI per year for non-significant lesion, DEFER: **1%.**

Fractional Flow Reserve

Comparison between FFR and visual assessment and QCA

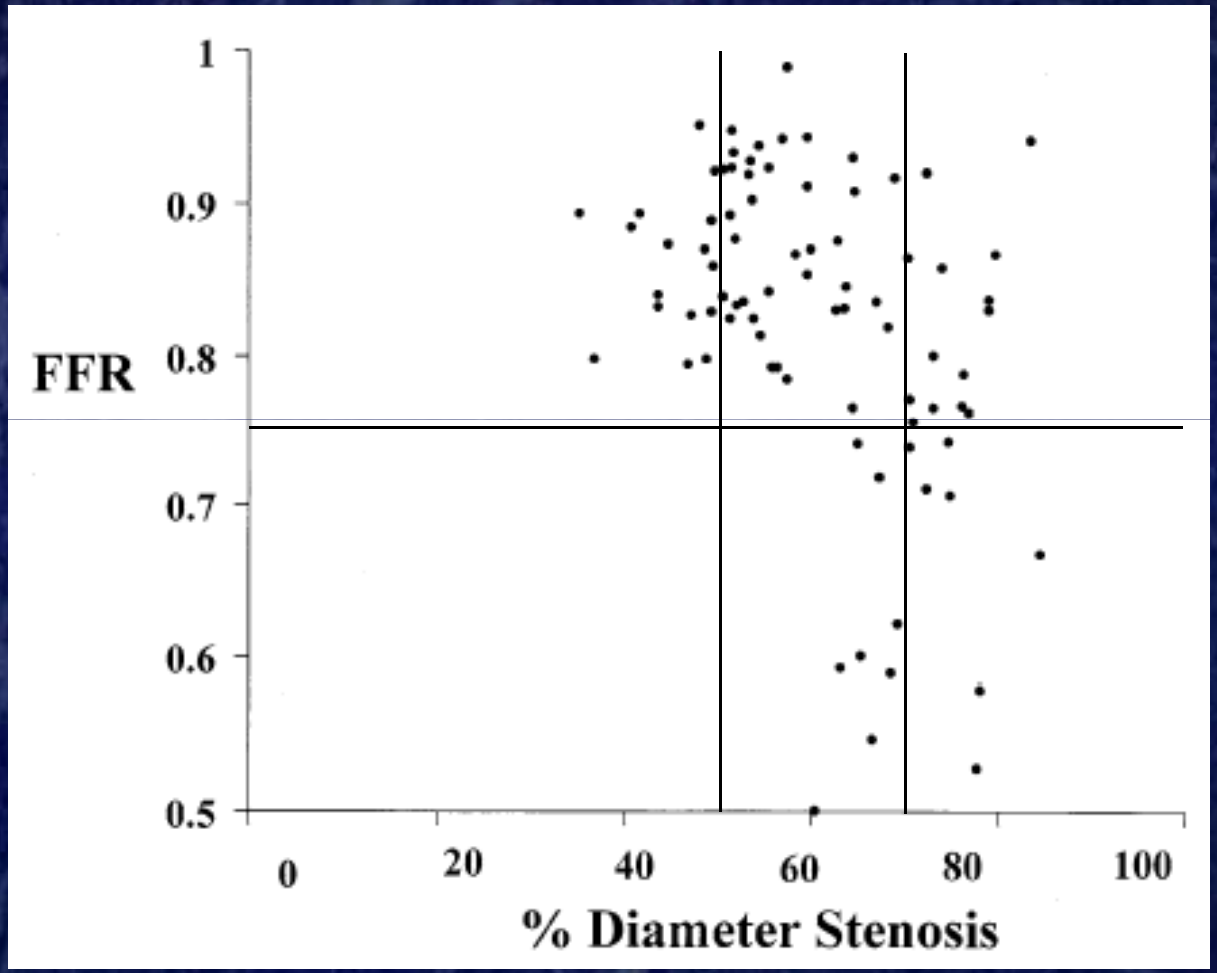
83 moderate lesions (40-70%)

- Three experienced interventionalists (UVa)
- FFR = 0.82 ± 0.11, <0.75 in 15 (18%)

		Visual Estimate		
		Pos (44)	Neg (39)	
FFR	Pos (15)	12	3	Sens 80%
	Neg (68)	32	36	Spec 47%
		PPV 25%	NPV 91%	

Fischer et al, Am J Cardiol 2002

Relationship Between QCA and FFR



Fischer et al, Am J Cardiol 2002

Clinical Uses

- Indeterminate lesions
  - Moderate, intermediate stenosis (30-70%)
  - Left main disease
  - Ostial disease
- Tandem lesions, diffuse disease
- Multi-vessel disease
- Non-coronary uses – renal arteries

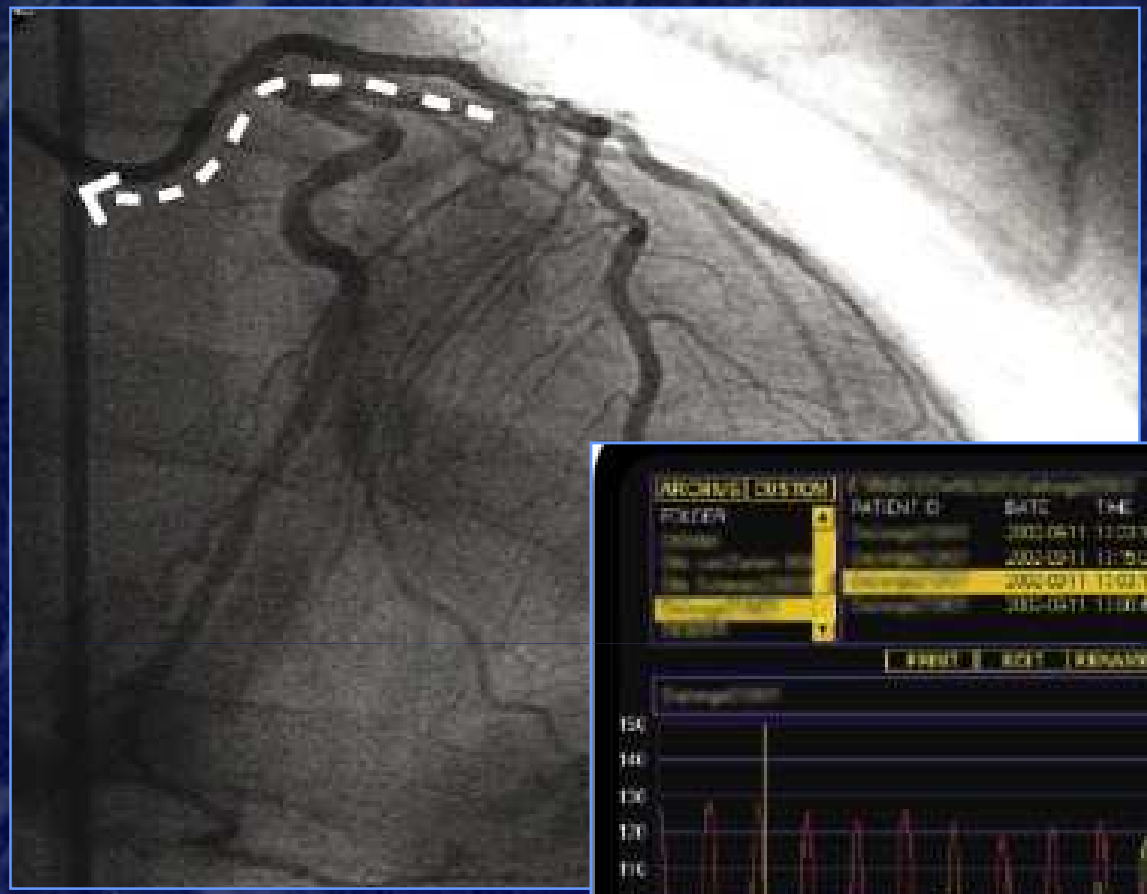
Clinical Uses

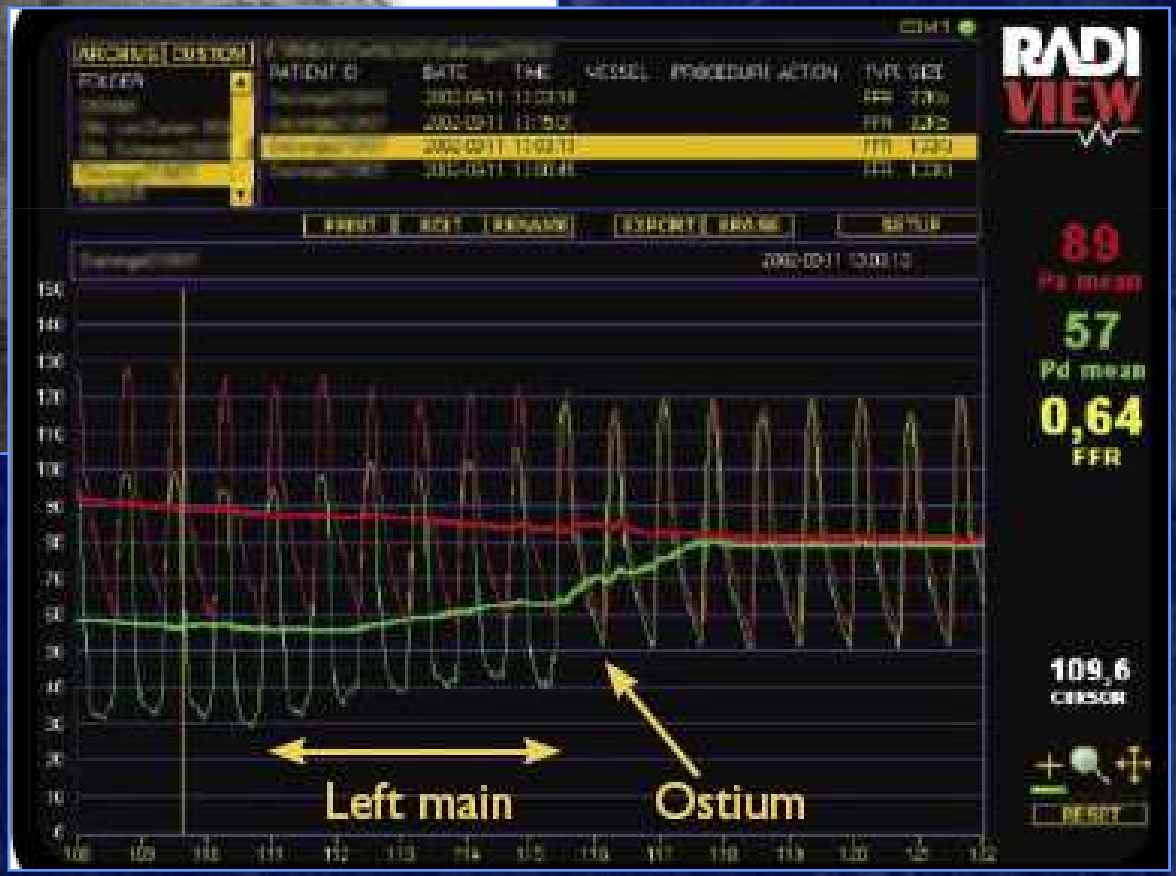
Class IIa

It is reasonable to use intracoronary physiologic measurements (Doppler ultrasound, fractional flow reserve) in the assessment of the effects of intermediate coronary stenoses (30% to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive functional testing (e.g., when the functional study is absent or ambiguous) to determine whether an intervention is warranted. *(Level of Evidence: B)*

ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention, JACC, January 3, 2006

Equivocal Left Main Disease





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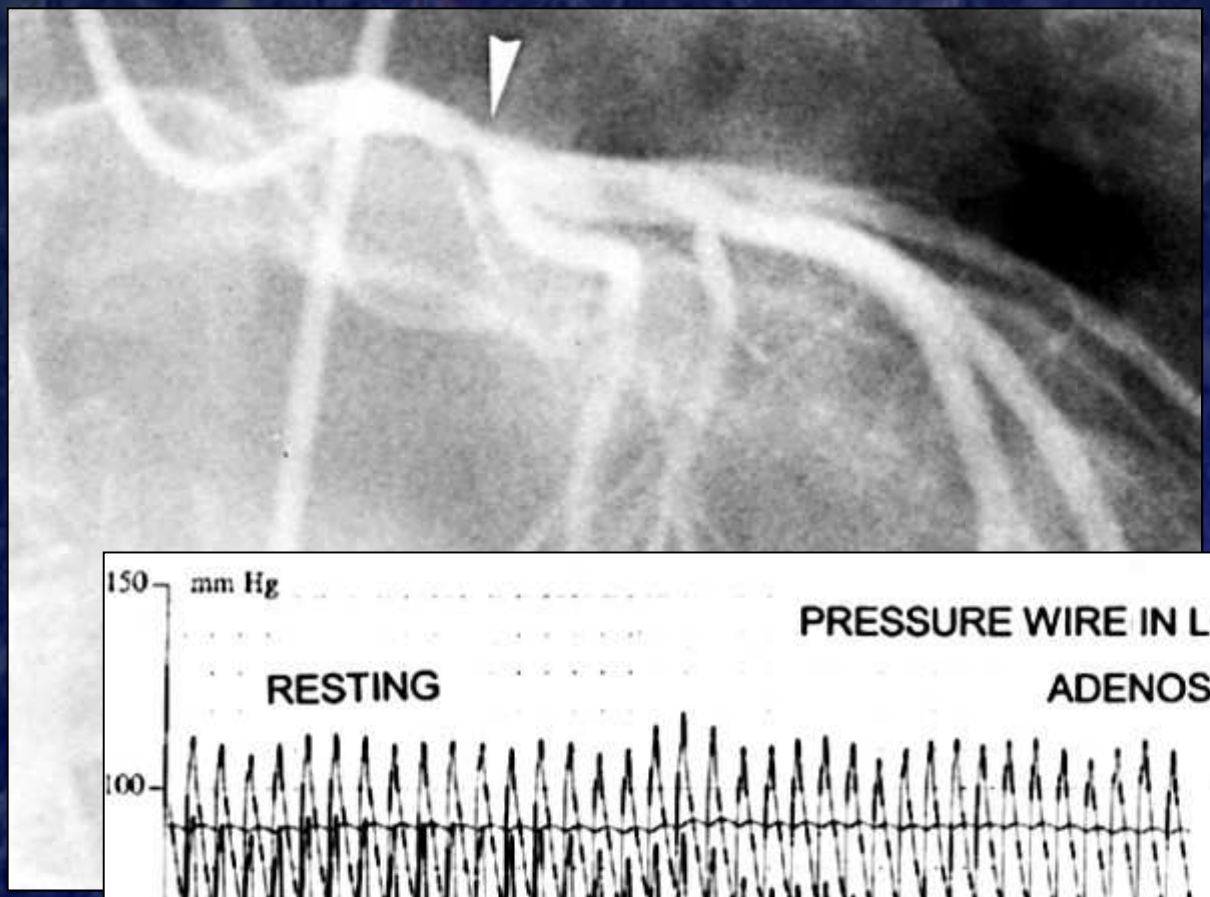
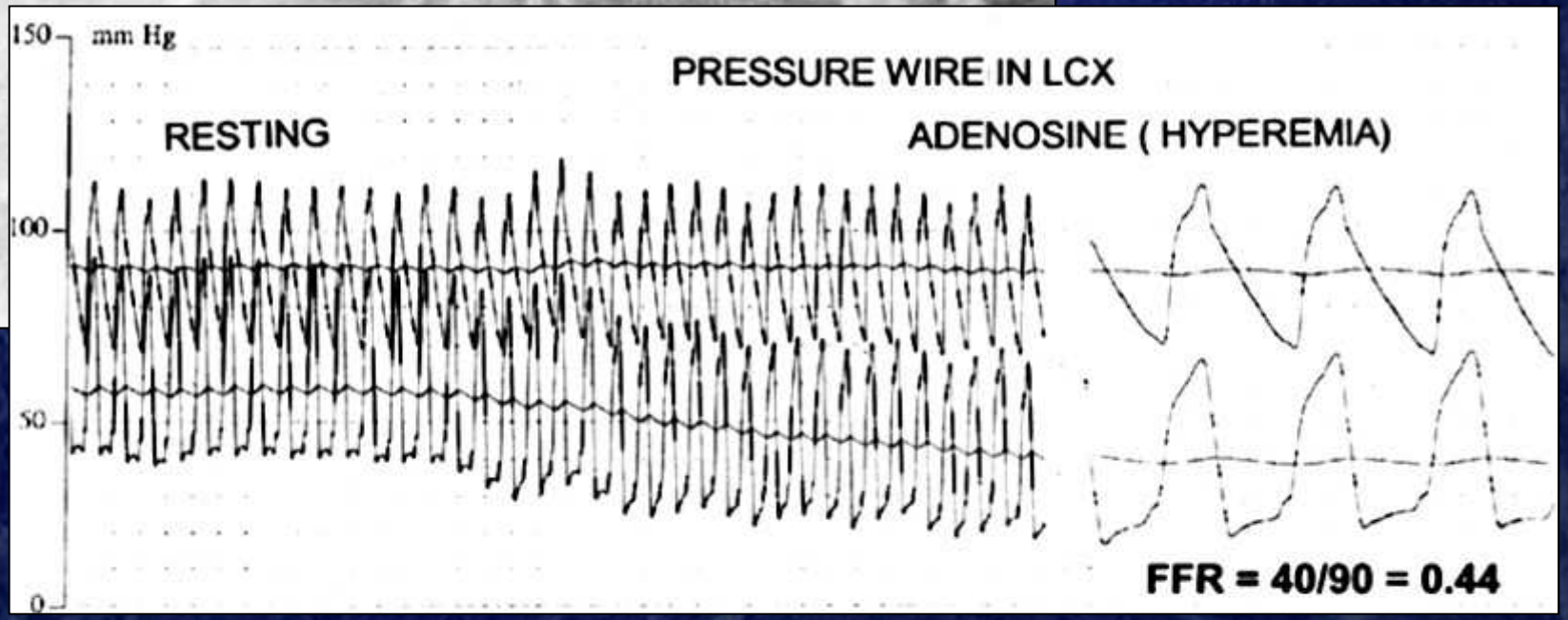
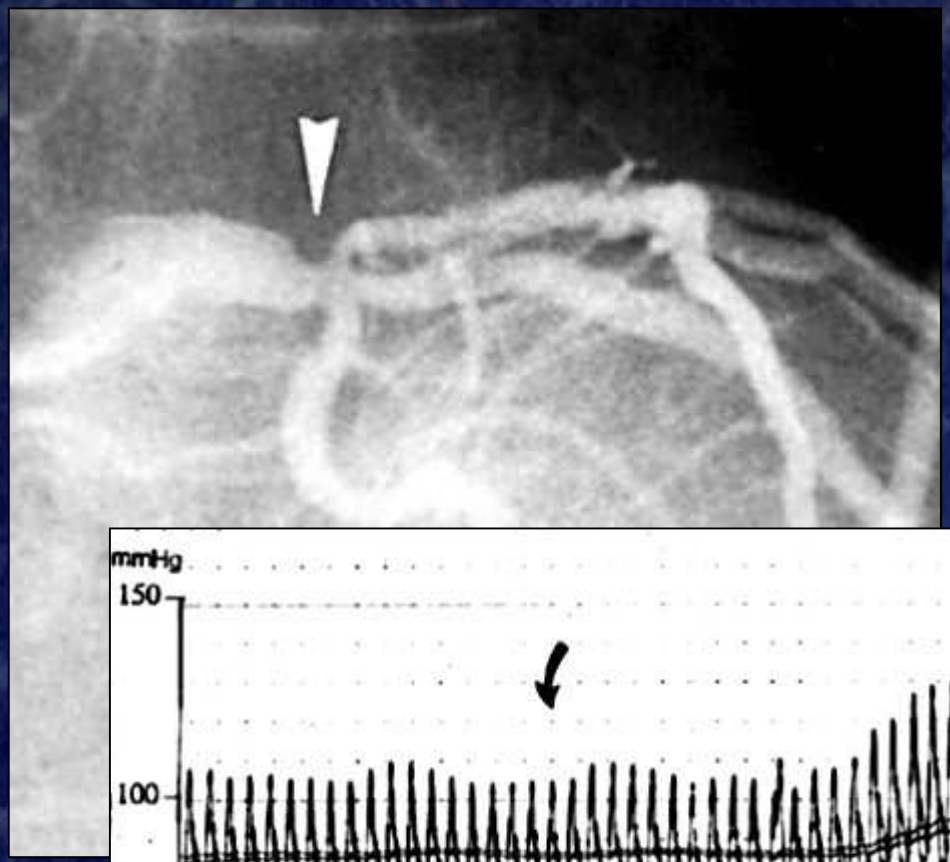
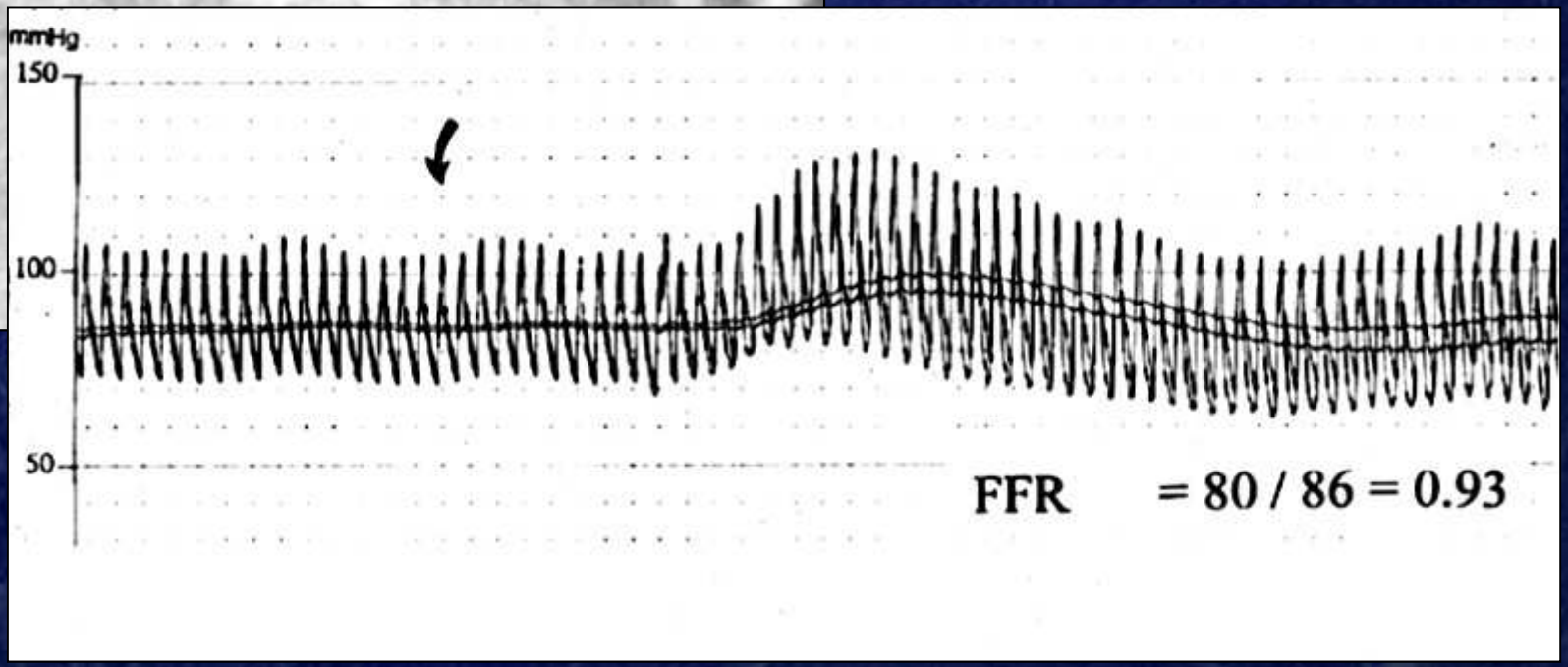




Bech et al, Heart 2001

Equivocal Left Main Disease

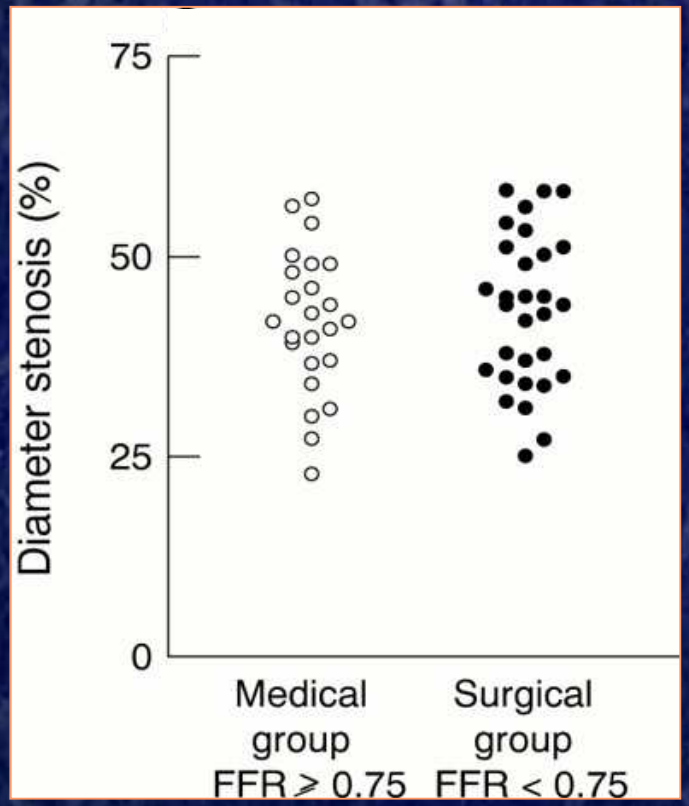


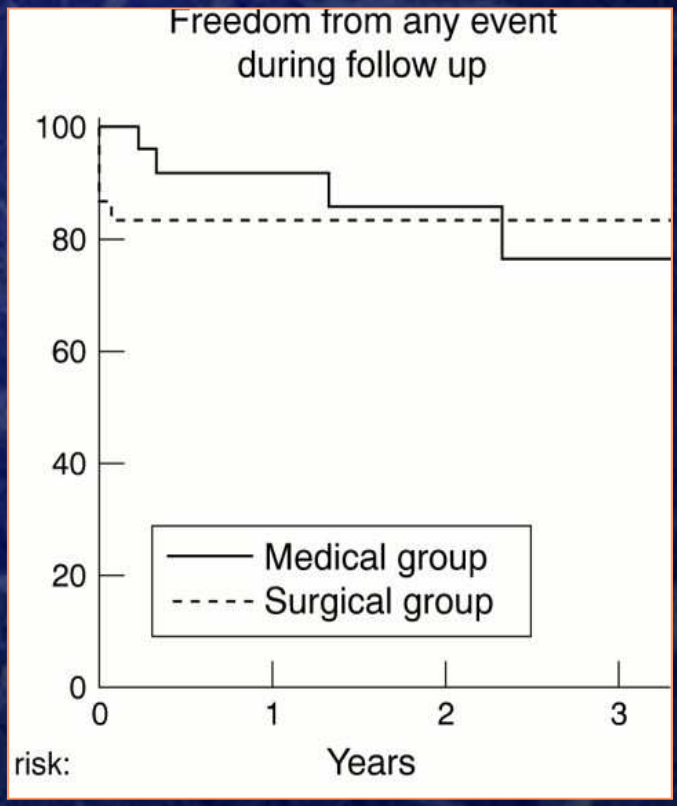


Bech et al, Heart 2001

FFR_{myo} and Equivocal Left Main Disease

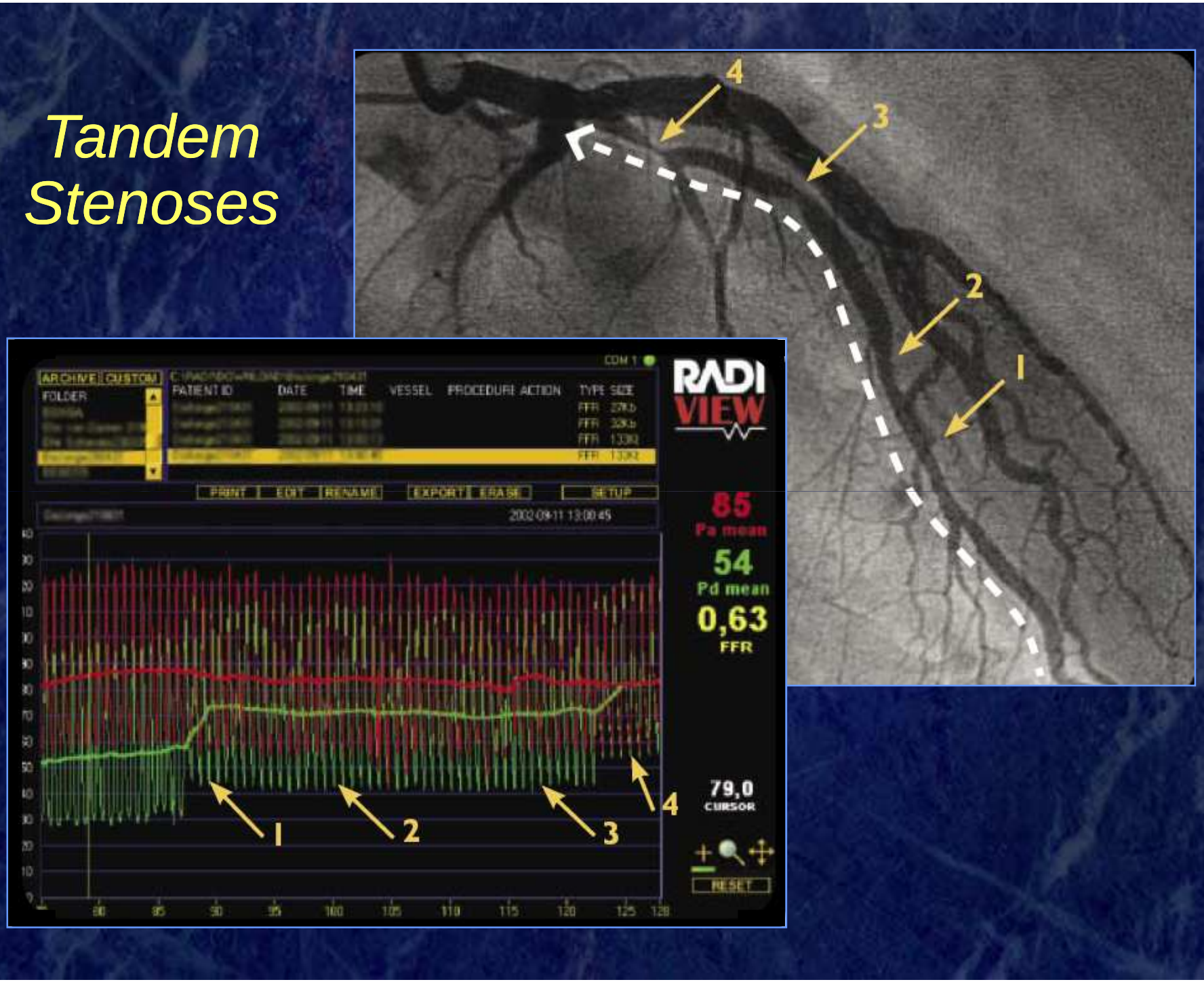
- 54 Consecutive patients with angiographically equivocal left main disease



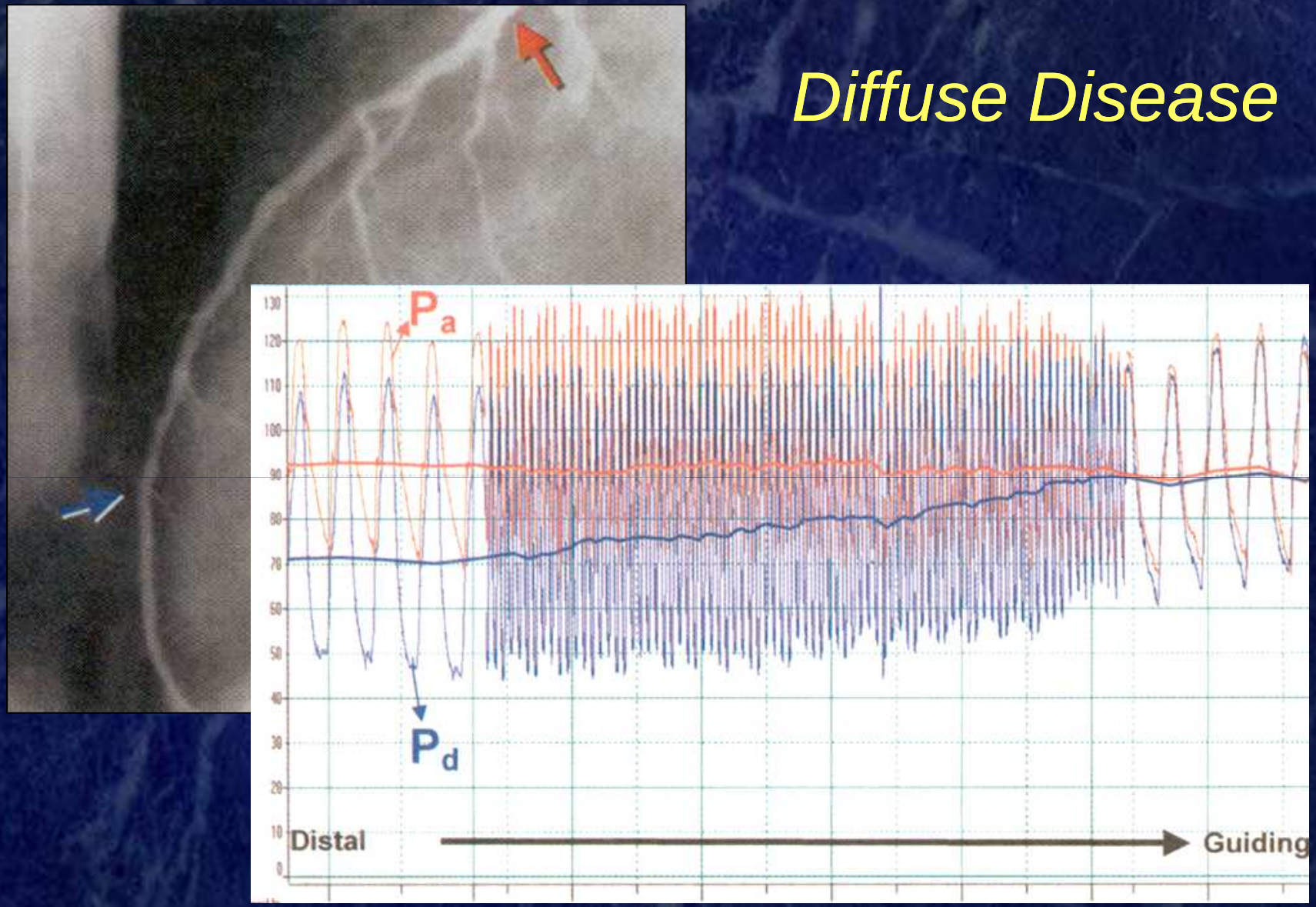


Bech et al, Heart 2001

Tandem Stenoses

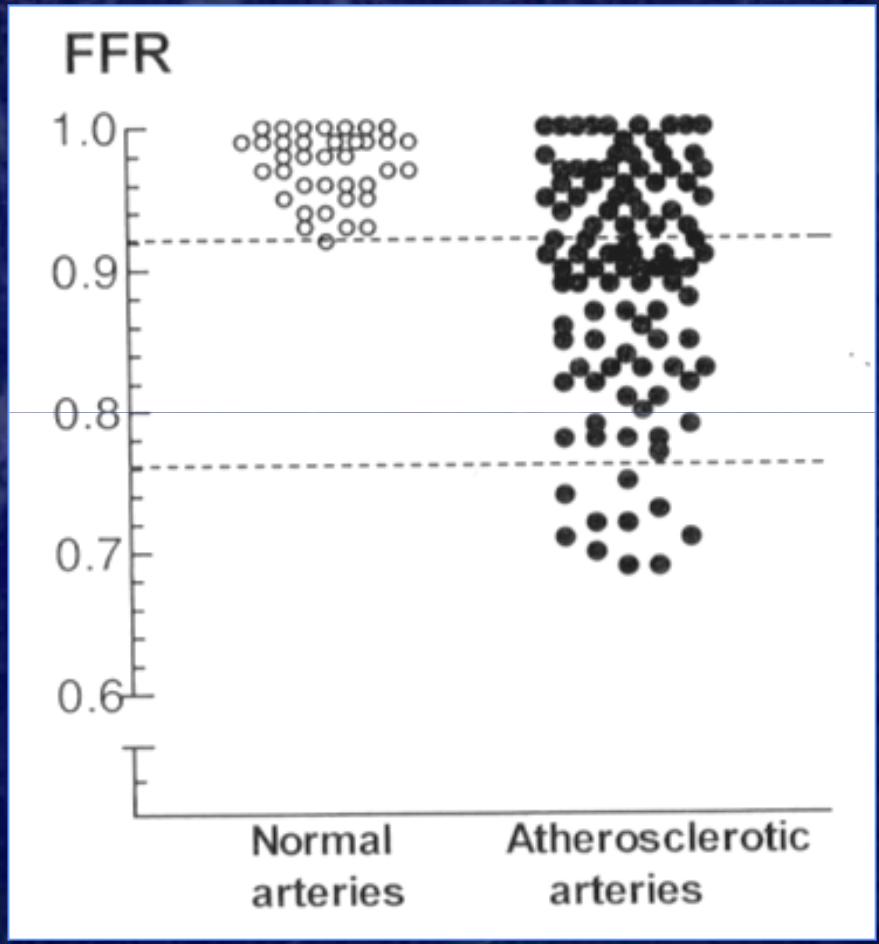


Diffuse Disease



DeBruyne et al, Circulation 2001

FFR_{myo} and Diffuse Disease



DeBruyne et al, Circulation 2001

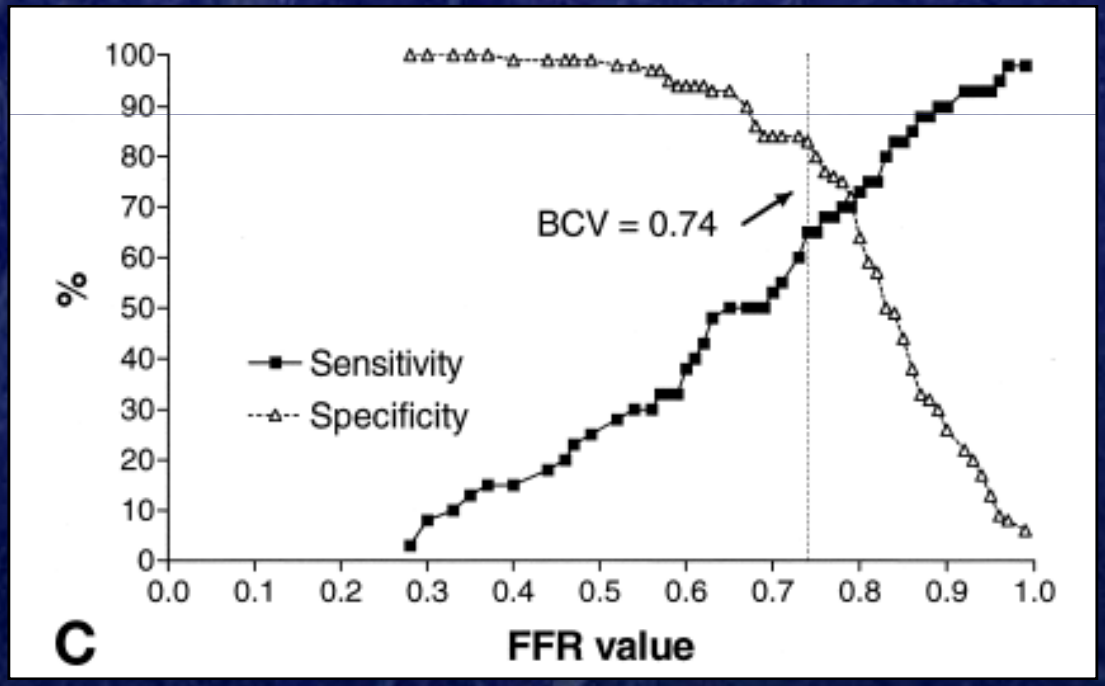
FFR_{myo} and Multi-Vessel CAD

Diagnostic Accuracy

Dipyridamole MIBI-SPECT performed in 127 patients

CFVR, rCFVR, FFR performed in 161 lesions

Predictive value assessed by AUC of ROC curves



Chamuleau et al, J Am Coll Cardiol 2001

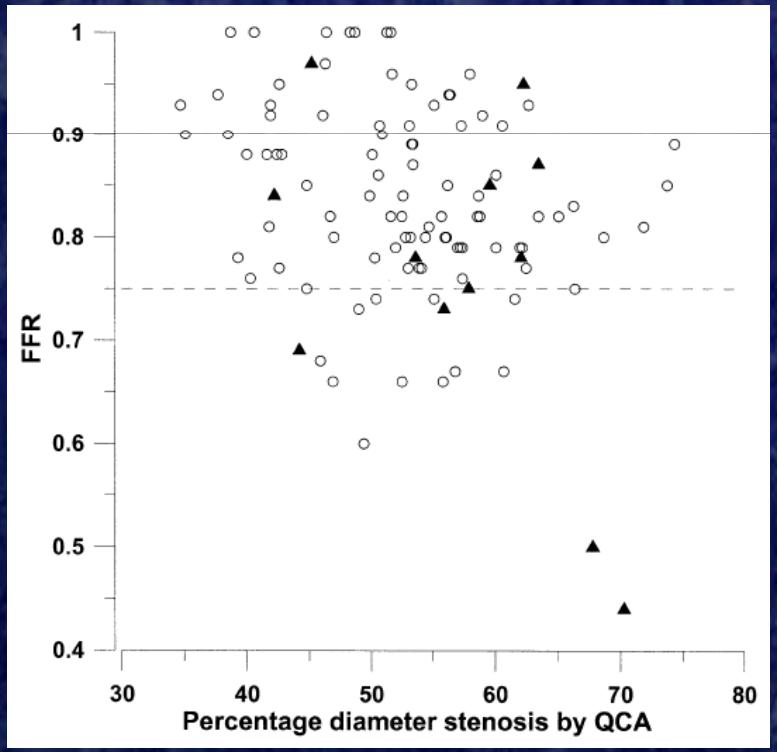
FFR_{myo} and Multi-Vessel CAD

Clinical Decision-Making and Risk Stratification

107 patients, MVD referred for PCI, additional intermediate lesion

Normal perfusion scintigraphy in region of intermediate lesion

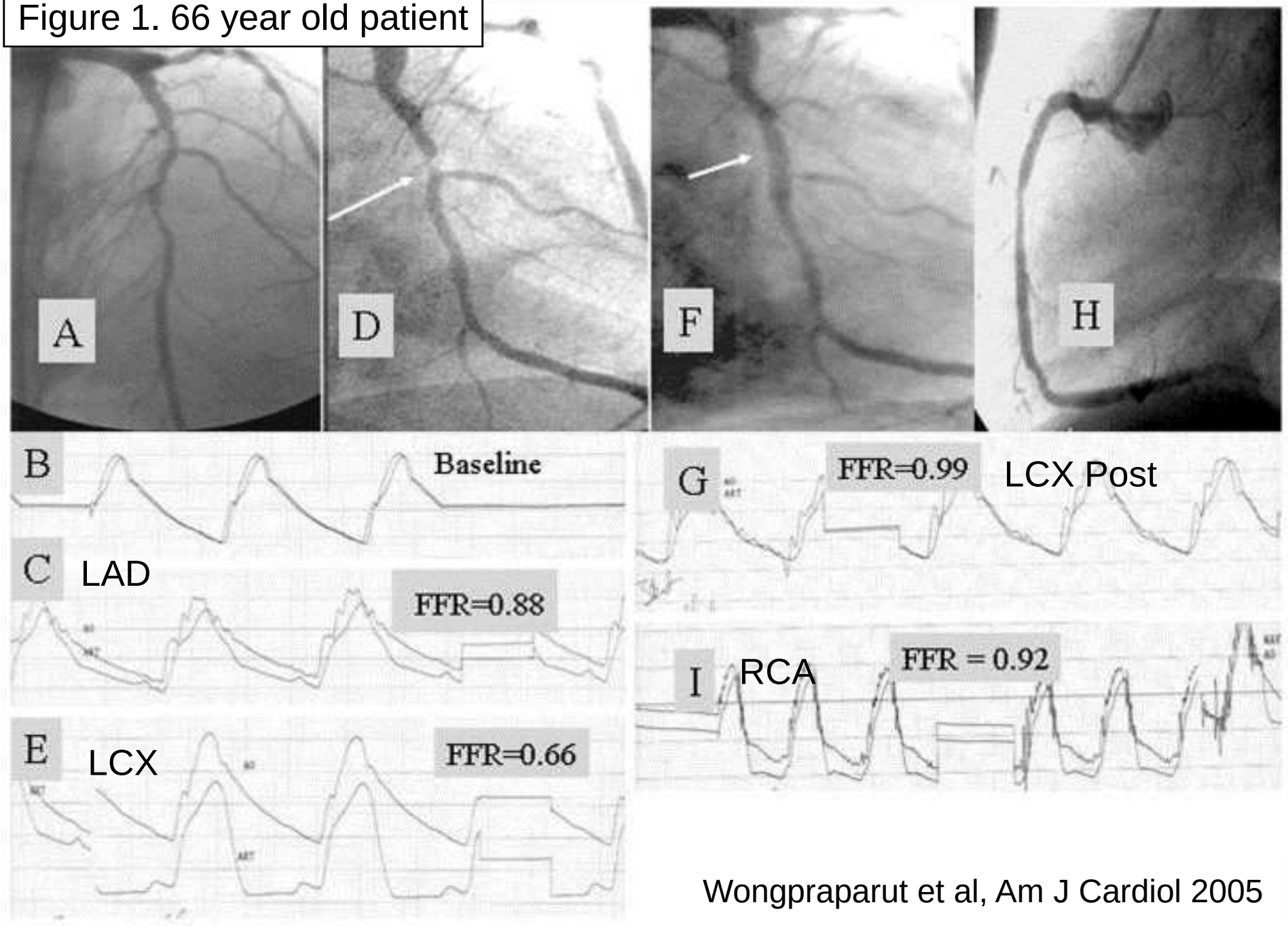
FFR measured and patients followed 1 year



- FFR abnormal in 15/107 (14%)
- 12 events (no deaths, 3 MI, 2 CABG, 7 PCI)
- 27% vs 9% with FFR >0.75 (RR 3.1, $p<0.05$)

Chamuleau et al, Am J Cardiol 2002

Figure 1. 66 year old patient



Wongpraparut et al, Am J Cardiol 2005

Multi-Vessel CAD
FFR vs Angiographic Guidance

137 consecutive patients with multi-vessel disease treated with PCI guided by angiography or FFR (non-randomized)

	FFR-PCI	Angio-PCI	P-Value
% vessels PCI deferred	58%	0%	<0.001
% vessels PCI performed	42%	100%	<0.001
# vessels treated / pt	1.12 ± 0.30	2.27 ± 0.54	<0.001
# stents / pt	1.04 ± 0.49	1.28 ± 0.92	<0.001

Wongpraparut et al, Am J Cardiol 2005

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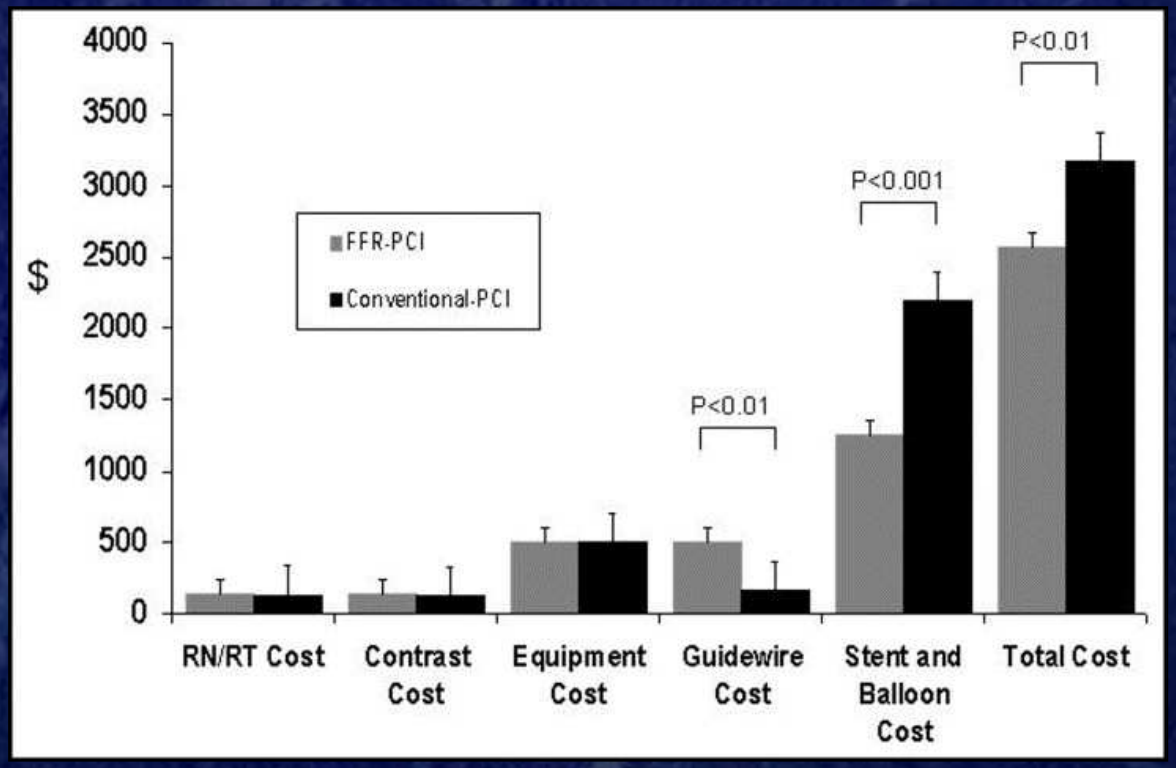

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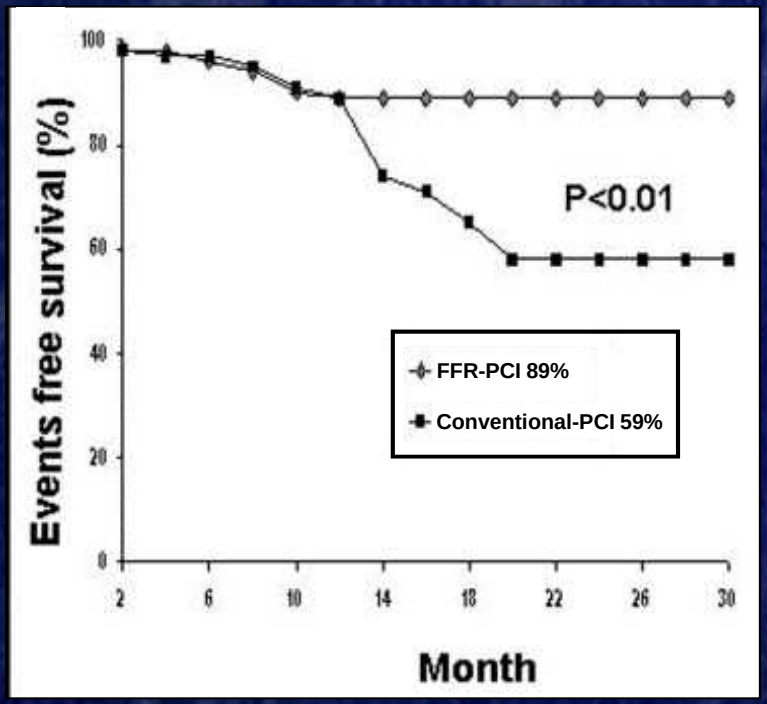


Event	FFR-PCI	Angio-PCI
In-Hospital MACE	14%	23%
F/U MI	1	6
F/U Revasc	5%	23%
Death	3	3
F/U MACE	8%	27%

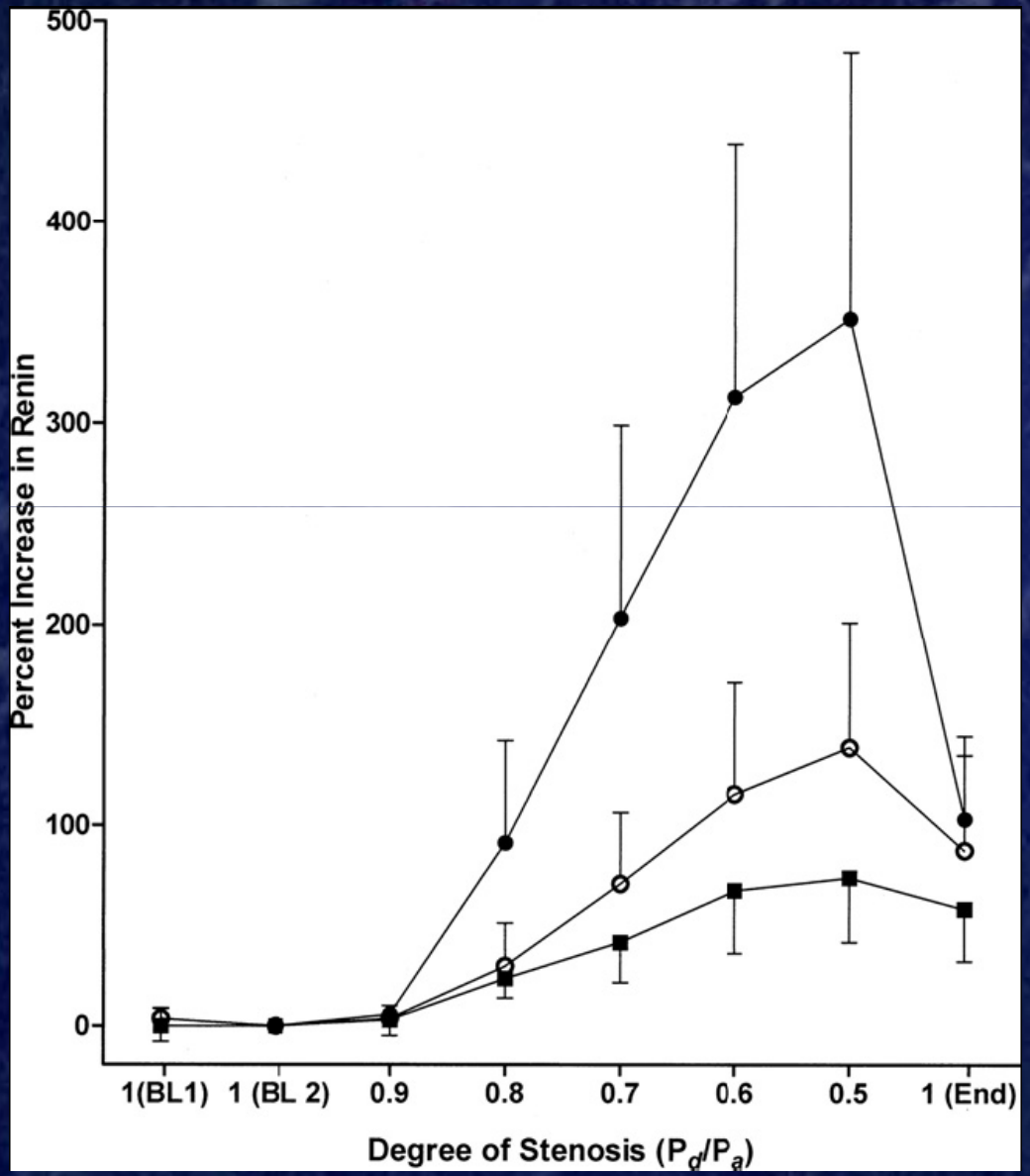
Wongpraparut et al, Am J Cardiol 2005

Renal Pressure Measurements

- **"When measured clinically, trans-stenotic pressure gradients are most commonly assessed with a fluid-filled end-hole catheter. Unfortunately, this technique may be limited by obstruction of the vessel with the catheter, actually increasing the TSPG."**
- **"…the 4 FR catheter occupies 24% of the vessel diameter. In contrast, the PressureWire would occupy only 6% and therefore introduces less artifact into the measurement gradient."**
- **"(A pressure-sensing guidewire) provides a more reliable indication of stenosis significance than the use of a 4 FR catheter."**

Colyer et al, Caridovascular Catheterizations and Interventions, 2003

Renal Pressure Measurements



Effects of a balloon-induced, unilateral, controlled, graded stenosis (expressed as P*d* /P*a* ratio) on plasma renin concentration in the aorta **(squares)**, in the vein of the stenotic kidney **(closed circles)**, and in the vein of the non-stenotic kidney **(open circles)**. BL 1 baseline before stenting; BL 2 baseline after stenting; other abbreviations as in Figure 2.

DeBruyne, et al. JACC Vol. 48, No. 9, 2006

Cost-effectiveness of FFR to Guide PCI

Three strategies:

- NUC strategy - Defer PCI for nuclear test
- FFR strategy - Measure FFR to guide PCI decision
- STENT strategy - Stent ALL intermediate lesions

Findings:

1. FFR vs. NUC = $1795 per patient saved
2. FFR vs. STENT = $3830 per patient saved
3. QALY similar among the 3 strategies
4. Both FFR and NUC were superior to (less cost, better outcomes) STENT strategy

Conclusions: In patients with an intermediate coronary lesion and no prior functional study, measuring FFR to guide the decision to perform PCI may lead to significant cost savings compared with performing nuclear stress imaging or with simply stenting lesions in all patients

Fearon et al, Am Heart J 2003

Impact On Patient Care

- Safe, fast, and cost-effective
- Application of evidence-based medicine
- Superior to angiography alone for identifying significant lesions

Need For New ICD-9-CM Codes

- Existing coding is inadequate and imprecise
- Need to distinguish coronary from several non-coronary applications
- Need to track product costs and resource utilization
- Codes facilitate more accurate coding for reimbursement
- Same rationales supported recent creation of analogous IVUS codes